



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 7 1994

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: PP#4F04314. Product Chemistry Review and Request for Exemption from a Tolerance for the Biochemical Active Ingredient **1,4-Dimethylnaphthalene**. The End-Use Product **1,4-SIGHT®** Is Intended to Inhibit Sprouting in Stored Potatoes.

MRID#s 430825-01 thru -09 and 432668-01 thru -03
(13 vols.).

DP Barcodes#: D204771, D204773, D207820.

CBTS#s: 13930, 13931, 14444.

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To: Cynthia Giles-Parker/James Stone, PM Team 22
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E.R. Butts International, Inc., acting as the agent and regulatory consultant for the registrant, D-I-1-4, Inc., has submitted product and residue chemistry data to support the registration of the biochemical sprouting inhibitor **1,4-dimethylnaphthalene** for use on potatoes.

Background

1,4-dimethylnaphthalene was classified as a biochemical 3/23/93. The classification was based on 1,4-dimethylnaphthalene's natural occurrence and its acting as a plant growth regulator (in this case as a sprouting inhibitor). The registrant provided information to show that 1,4-dimethylnaphthalene occurs naturally in potatoes at levels between 1 and 10 ppm. When conditions are right for sprouting, the potato metabolizes the 1,4-dimethylnaphthalene to low enough levels that sprouting can occur. 1,4-dimethylnaphthalene is intended to be a safer replacement for chlorpropham.

Proposed Use

The end-use product, 1,4SIGHT will be applied to stored potatoes using a fogging system similar to the way chlorpropham can be applied. One gallon of 1,4SIGHT contains 8 lbs of active ingredient and will treat 400,000 lbs of potatoes (2.5 ppm). Up to 4 applications may be made during the storage season, which generally runs from October to August. No minimum time period between treatment and consumption was explicitly specified, but the label contains language that the product will not be sprayed on stored potatoes during the retail packing process.

Conclusions and Recommendations

As noted in the main body of this memo, additional data are necessary in order to fulfill the following guidelines:

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|--------|--|
| 151-12 | Discussion of the Formation of Unintentional Ingredients |
| 151-13 | Analysis of Samples |
| 151-15 | Certification of Ingredient Limits |
| 151-16 | Analytical Methods for Certified Limits |
| 151-17 | Physical and Chemical Properties |

However, based on the nature of the product, CBTS does not believe that the outstanding data necessitate a delay in the registration of the product. Therefore, TOX considerations permitting (as noted in section 151-12), CBTS can recommend that RD issue a conditional registration for 1,4-dimethylnaphthalene provided that the additional data are supplied at a later date (to be determined by RD).

Note to PM:

CBTS defers the review of end-use products to the Registration Division (RD).

Detailed ConsiderationsProduct Chemistry

Note: Some of the confidential material in this petition have been photocopied and placed in a Confidential Appendix. However our conclusions on each guideline number appear below in the non-confidential portion of the review.

151-10 Product Identity and Disclosure of IngredientsProduct Identity

1,4SIGHT contains the active ingredient 1,4-dimethylnaphthalene.

Confidential Statement of Formula

Data for the Confidential Statement of Formula (CSF) for 1,4-dimethylnaphthalene were submitted and are found in Confidential Appendix Part A, which was photocopied directly from the petition.

Information on Ingredients

Information on the active ingredient is listed in Table 1 below. Information on the impurities are in Table 2 under section 151-10 of the Confidential Appendix.

Table 1

Supplied Information on Active Ingredient

Name	1,4-dimethylnaphthalene
CAS#	571-58-4
Empirical Formula	C ₁₂ H ₁₂
Molecular Weight	156.2
% in Product (weight)	94.7%

Information on the starting materials for the manufacturing processes were submitted and are found in Confidential Appendix Part B, which was photocopied directly from the petition.

CBTS Response to 151-10

CBTS considers the CSF and information on the active ingredient and impurities adequate to fulfill the requirements of 151-10.

151-11 Manufacturing Process

Descriptions of the manufacturing processes for 1,4-dimethylnaphthalene are provided in the Confidential Appendix Part C, which was photocopied directly from the petition.

CBTS Response to 151-11

CBTS considers the descriptions of the manufacturing processes adequate to fulfill the requirements of 151-10.

151-12 Discussion of the Formation of Unintentional
Ingredients

The discussion on the formation of unintentional ingredients associated with the manufacture of 1,4-dimethylnaphthalene are provided in the Confidential Appendix Part D, which was photocopied directly from the petition.

CBTS Response to 151-12

Based on our review of the manufacturing processes provided by the petitioner (see CBTS response to 151-11) and the discussion on the formation of unintentional ingredients provided by the petitioner, CBTS does not expect that nitrosamines, HCBs, dioxins, or other trace, toxicologically significant impurities will be produced in the manufacture of 1,4-dimethylnaphthalene. However, CBTS defers any judgement on the toxicity of any impurities in the product to TOX and the toxicology tests performed using the technical product. Additional discussion is needed on the newly identified impurity (see CBTS Response to 151-13 in the Confidential Appendix of this memo).

151-13 Analysis of Samples

The petitioner provided the results from the analysis of the 1,4-dimethylnaphthalene technical product for levels of active ingredient and impurities. These are found in Confidential Appendix Part E.

The analytical methods for the analysis of the active ingredient and impurities in the 1,4-dimethylnaphthalene technical product were provided and are found in Confidential Appendix Part F.

CBTS Response to 151-13

See CBTS Response to 151-13 in the Confidential Appendix of this memo.

151-15 Certification of Ingredient Limits

The petitioner provided proposed upper and lower certified limits for the active ingredient, and upper certified limits for the impurities in the 1,4-dimethylnaphthalene technical product (see CSF in Confidential Appendix Part A).

CBTS Response to 151-15

See CBTS Response to 151-13 in the Confidential Appendix of this memo.

151-16 Analytical Methods for Certified Limits

The analytical methods for the analysis of the active ingredient and impurities in the technical product were submitted and are found in Confidential Appendix Part F (see CBTS Response to 151-13).

CBTS Response to 151-16

See CBTS Response to 151-13 in the Confidential Appendix of this memo. Other than the lack of an analytical method for the analysis of the newly identified impurity, CBTS considers the submitted methods adequate to fulfill the requirements of 151-16.

151-17 Physical and Chemical Properties

The registrant submitted a list of the physical and chemical properties for the 1,4-dimethylnaphthalene technical product, which are contained in Table 3 below.

Table 3

Physical and Chemical Properties of 1,4-Dimethylnaphthalene

Requirement	Guideline	Data
color	63-2	pale yellow
physical state	63-3	liquid
odor	63-4	petroleum distillates
melting point	63-5	N/A
boiling point	63-6	264°C @ 744 mm Hg.
specific gravity	63-7	1.014 @ 25°C
solubility	63-8	5.1 ppm in water
vapor pressure	63-9	1.88x10 ⁻² @ 25°C 3.64x10 ⁻² @ 35°C 8.75x10 ⁻² @ 45°C
dissociation constant	63-10	N/A
octanol/water partition coefficient	63-11	no data submitted
pH	63-12	6.3 (inert atmosphere), 5.9 (ambient atmosphere) for a 1% solution @ 25°C
stability	63-13	accelerated storage: test was negative (14 days @ 55°C) light stability: 13.7% decrease in weight (14 days @ 55°C) thermal stability: up to 7% loss at up to 150°C in both air and inert environments sensitivity to metals: no decomposition @ 100°C for 1 hour in the presence of aluminum, iron, and tin powders
flammability	63-15	122°C @ 760 mm Hg
explosibility	63-16	test was negative (drop height of 32.25 inches)
storage stability	63-17	no data submitted
viscosity	63-18	6 cps at both 12 and 30 rpm
miscibility	63-19	N/A
corrosion characteristics	63-20	test was negative (conducted on both HDPE and tin containers @ 50°C for 92 days)
dielectric breakdown voltage	63-21	N/A

CBTS Response to 151-17

The following 151-17 data are outstanding:

octanol/water partition coefficient (63-11)
storage stability (63-17)

The petitioner is referred to the Pesticide Assessment Guidelines, Subdivision M Section 151-17, and Subdivision D Sections 63-2 thru 63-21 for more guidance on these and other physical and chemical property requirements.

Attachment I : Confidential Appendix, including:

- Part A - Confidential Statement of Formula (1 page)
- Part B - Information on the Starting Materials (8 pages)
- Part C - Manufacturing Processes (8 pages)
- Part D - Discussion of the Formation of Unintentional Ingredients (2 pages)
- Part E - Certification of Ingredient Limits (2 pages)
- Part F - Analytical Methods for Certified Limits (8 pages)

cc (without attachments): circu., E. Haeberer (section head).

cc (with attachments): RF, SF (1,4 Dimethylnaphthalene),
G.J. Herndon.

RDI: Section Head: E. Haeberer: 10/4/94,
Acting Branch Chief: R. Loranger: 10/5/94.

H7509C: CBTS: G.J. Herndon: 305-6362: CM#2, Rm. 804C: 10/4/94.

